National Institute for Occupational Safety and Health (NIOSH)

Coal Workers' Health Surveillance Program (CWHSP)

Spirometer Manufacturer & Model Information for Clinics

Purpose: The National Institute for Occupational Safety and Health (NIOSH) operates the Coal Workers' Health Surveillance Program (CWHSP), which provides respiratory health screening and surveillance to U.S. coal miners. Under this program, coal miners are entitled to respiratory health screening via questionnaires, chest radiography, and spirometry upon entry into the coal mining workforce and then periodically throughout their careers.

In 2014, pursuant to revised Mine Safety and Health Administration's regulations, NIOSH promulgated 42 C.F.R. Part 37 of the Final Dust Rule, which established standards for the spirometry testing of coal workers to help to protect the respiratory health of the nation's coal mining workforce. NIOSH spirometry facility approval is an integral part of the CWHSP. Specific information on facility approval and spirometry testing can be found at 42 C.F.R. Subpart 37.9.

Approved CWHSP medical facilities interested in providing respiratory health screening for miners must use spirometers that:

- **Meet compliance with American Thoracic Society (ATS) performance standards.**
- **Satisfy specific NIOSH requirements regarding the content of spirometry test reports.**
- **Produce output data in standardized electronic spirometry data file format by February 2018.**

Electronic spirometry data files need to include **both flow-volume** and **volume-time** data points for each forced expiratory maneuver. This allows NIOSH to reconstruct individual maneuver spirometry curves for quality review of coal miner spirometry test reports.

The table below informs potential and participating CWHSP approved spirometry facilities of spirometers that currently meet or have expressed an interest in working towards meeting all NIOSH CWHSP regulatory requirements. Prior to February 2018, CWHSP approved clinics are able to submit to NIOSH CWHSP spirometry reports in PDF format. After February 2018, NIOSH requires that spirometry clinics submit CWHSP spirometry reports via electronic data transfer in CSV or XML format. Manufacturers currently not listed in the table and who are interested in furthering the objectives of this public health program can participate by ensuring their equipment meets NIOSH's regulatory standards and electronic data transfer capabilities. Information is available at: http://www.cdc.gov/niosh/topics/surveillance/ords/coalminerhealth.html. This table will be monitored and periodically updated to reflect which spirometer models either currently satisfy or are being modified to comply with NIOSH's spirometry reporting and electronic data transfer requirements.

Legal Authority: This program is authorized under the Federal Mine Safety and Health Act of 1977, 30 U.S.C. § 801 *et seq*.

Contact us at: NIOSHbreathe@cdc.gov if you have questions.

Disclaimer: This page is for informational purposes only and mention of any company, product, or service does not constitute endorsement on behalf of the National Institute for Occupational Safety and Health (NIOSH), the Centers for Disease Control and Prevention (CDC), or the U.S. Department of Health and Human Services (HHS), or imply that any company or its products or services is preferred over any other.

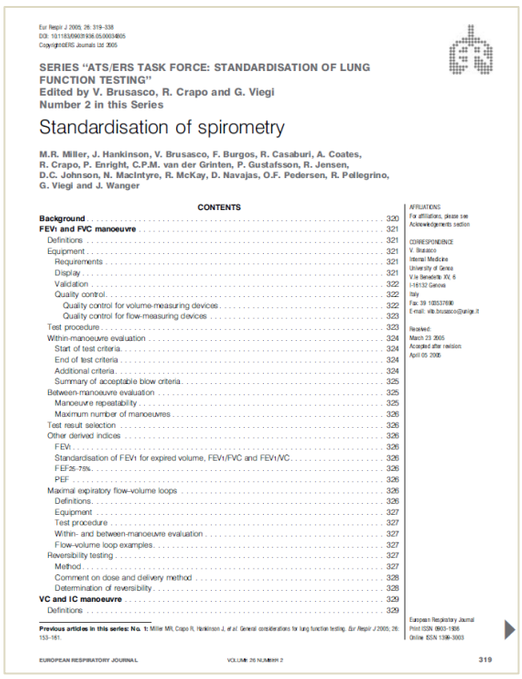
NIOSH CWHSP Spirometer Table

Manufacturer	Model	Actively working with NIOSH CWHSP	CWHSP PDF Report printout (good until Feb. 2018)	Manufacturer actively developing Electronic Data Transfer for this Model	Electronic Data Transfer Capable (good after Feb. 2018)
CareFusion	Vmax Vyntus SPIRO	*	*	*	
	Masterscreen (with SentrySuite)	*	*	*	
	Masterscreen (w/o SentrySuite)	*	*		
	Vmax Autobox V62J (if with SentrySuite)	*	*	*	
	Vmax Autobox V62W (if with SentrySuite)	*	*	*	
	Jaeger Vyntus (if with SentrySuite)	*			
Cohero Health/Thor	SpiroDesk	*			
CosMed	Microquark	*	*	*	
	Pony HF	*			
eResearch Technology	Masterscope	*			
MCG Diagnostics	Platinum Elite (2009)	*	*		
	Platinum Elite +RTD	*	*		
	Ultima	*			
	Ultima PFX	*			
	CPFS/D	*			
Midmark Corporation	IQSpiro	*			
	Brentwood by Midmark (2000)	*			
	IQMark	*			
MIR (Medical International Research)	Spirolab	*			
	Minspir	*			
Morgan Scientific	Pneumotrac	*	*	*	
	TransAir3	*			
	Body Plethysmograph	*	*	*	
ndd Medical Technologies, Inc.	Easy on-PC	*	*	*	*
	EasyOne (with PC cable)	*	*	*	*
	EasyOne Pro LAB	*	*	*	*
nSpire	KoKo PFT	*	*		
	KoKo Digidoser	*	*		
Vitalograph	Pneumotrac	*	*	*	
	ALPHA Touch	*		*	
	COMPACT Workstation	*		*	
Welch Allyn	SpiroPerfect	*	*	*	

***Table Last Updated*: 6/23/2016**

Contact us at: NIOSHbreathe@cdc.gov if you have questions.

Spirometry Testing Equipment


Eur Respir J 2005; 26: 319–338
DOI: 10.1183/09031936.05.00034805
Copyright©ERS Journals Ltd 2005

SERIES "ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING"
Edited by V. Brusasco, R. Crapo and G. Viegi
Number 2 in this Series

Standardisation of spirometry

M.R. Miller, J. Hankinson, V. Brusasco, F. Burgos, R. Casaburi, A. Coates, R. Crapo, P. Enright, C.P.M. van der Grinten, P. Gustafsson, R. Jensen, D.C. Johnson, N. MacIntyre, R. McKay, D. Navajas, O.F. Pedersen, R. Pellegrino, G. Viegi and J. Wanger

CONTENTS

AFFILIATIONS
For affiliations, please see Acknowledgements section.
CORRESPONDENCE
V. Brusasco
Internal Medicine
University of Genoa
V.le Benedetto XV, 6
I-16132 Genova
Italy
Fax: 39 1035337690
E-mail: vito.brusasco@unige.it

Received:
March 23 2005
Accepted after revision:
April 05 2005

Previous articles in this series: No. 1: Miller MR, Crapo R, Hankinson J, *et al*. General considerations for lung function testing. *Eur Respir J* 2005; 26: 153–161.

European Respiratory Journal
Print ISSN: 0903-1936
Online ISSN: 1399-3003

Spirometry testing equipment must meet the [2005 ATS/ERS Standardisation of Spirometry](#) specifications for spirometer accuracy and precision (Table 6, page 332) and real-time display size. It is the facility's responsibility to ensure that the equipment meets the requirements for testing; the facility cannot rely on a manufacturer's claim that the equipment meets the recommendations of the ATS/ERS, NIOSH, or any other professional or government entity.

1. A written verification letter pertaining to successful completion of 24 waveform testing from a third-party laboratory is required for each spirometer model prototype as outlined by the 1994 ATS Standardization of Spirometry Update. This validation letter should be obtained from the manufacturer.

2. The spirometry system must have a calibration check routine consistent with the 2005 ATS/ERS Standardisation of Spirometry.

3. Graphical displays must provide real-time volume-time and flow-volume curves during the test. These displays must meet or exceed a minimum size.

4. The spirometer software must automatically perform quality assurance checks on expiratory maneuvers during each spirometry testing session.

5. **a.** Each spirometer must contain enough active memory to store absolute values from at least 8 maneuvers within one testing session.

   b. The spirometry software must have the capacity to save and recall curves and results preferable from all maneuvers, but at a minimum for 3 acceptable maneuvers.

6. The spirometry data file must retain a record of the parameters defined in the 2005 ATS/ERS Standardisation of Spirometry (Table 8, page 335).

7. Spirometers that provide electronic transfer of spirometry data results files must use either a NIOSH-approved procedure or the format, content, and data structure specified by the 2005 ATS/ERS Standardisation of Spirometry (page 335).

Contact us at: NIOSHbreathe@cdc.gov if you have questions.